

REMARKS

This Amendment is filed in response to the Office Action dated July 6, 2009. Applicant has amended Claim 1. Following these amendments, the application includes Claims 1, 3, and 21. Applicant respectfully submits that the pending claims are patentable and respectfully requests reconsideration in light of the following remarks.

The Office Action rejects claims 1 and 21 in accordance with 35 U.S.C. 102(b) as being anticipated by Barreras, Sr. et al (5895416). In this regard, the Office Action draws the readers attention to various figures that *Barreras* describes as providing a diagrammatic representation of the size and location of an electric field and how same can be modified by the neural stimulating system of *Barreras* to achieve a Paresthesia effect covering the pain area without recruiting unwanted nerve tissue (refer column 6, lines 39 to 42).

Further, *Barreras* describes that depending on the anodic current assigned to each electrode, and which electrode(s) serve as the cathode, the size and location of the stimulating field, A,B or C, can be modulated for the purpose of recruiting only the target nerve tissue and exclude unwanted nerve tissue (refer column 6, lines 49 to 53).

In particular, while Figure 12 provides a diagrammatic representation displaying a range of electrical current paths between individual electrodes, *Barreras* describes the representative example of Figure 12 with reference to the fact that while only three electric fields are shown it is obvious that many more are possible (refer column 6, lines 54 and 55).

In any event, the diagrammatic representations in Figures 10, 11 and 12 of *Barreras* describes the location of surgically implantable electrodes for the control of nerve or brain response to treat intractable pain. In particular, while a range of electric fields residing between the electrodes are possible, the disclosure of *Barreras* is directed to the selection of a single electric field arrangement with ion flow (electrical current flow) passing from and to specific electrodes that does not vary over time.

In this regard, the problem addressed by the disclosure of *Barreras* is a distinctly different problem as compared with that of the present invention. In particular, *Barreras* describes his disclosure as relating to a method and apparatus for electrically and selectively

stimulating specific nerves tissue in a living creature (refer column 1, lines 8 to 9). Further, the method and apparatus described by *Barreras* is directed to circuitry for automatically changing the voltage amplitude at each anode in response to changes in the electrode impedance in order to maintain a constant anodic current, thereby preserving, for the duration of the therapy, the original electric field found to be most effective at implant time (refer column 1, lines 18 to 23).

In accordance with the stated objective of *Barreras*, the disclosure relates to the provision of a partially or completely implanted neurological stimulator connected to at least one stimulating lead incorporating at its distal end three or more electrodes with the stimulator being capable of, amongst other things, automatically changing the voltage amplitude at each anode in response to changes in electrode impedance in order to maintain a constant anodic current, thereby preserving, for the duration of the therapy, the original electric field found to be effective at implant time (refer column 2, lines 34 to 48).

In contrast, the stated objective of the instant application is the variation of electrical current between electrodes during a treatment in order to provide greater uniformity of electrical current distribution through the tissue of a subject under treatment. In order to clarify this aspect of the invention an amendment to claim 1 is proposed wherein the reference to the “intermittent” formation of probes as active probes or return probes causing establishment of electrical currents passing through different paths through the subject is amended to replace the word “intermittent” with “a repeatedly varying”.

Accordingly, the claims of the instant application now recite the activation of at least one switching control device during a treatment to cause “a repeatedly varying formation of probes as active or return probes...”. This is a distinctly different arrangement as compared with the disclosure of *Barreras* wherein the formation of electrical currents between probes is maintained (not varied) during the period of time for which pain relief is provided to the patient. Accordingly, the applicant respectfully submits that in view of the proposed amendment to claim 1 all of the claims should be considered novel in view of *Barreras*.

The Office Action also rejects claim 3 as being unpatentable in accordance with 35 U.S.C. 103(a) considering the disclosure of *Barreras*. In particular, the Office Action states that it would have been obvious to one having ordinary skill in the art at the time the invention was

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made to modify the stimulation system as taught by *Barreras* with the use of multiplexing devices.

Applicant respectfully disagrees in view of the teaching of the disclosure of *Barreras*, which is clearly directed to maintaining a constant anodic current between electrodes thereby preserving, for the duration of the therapy, the original electric field found to be most effective at implant time (refer column 1, lines 20 to 23, column 2, lines 44 to 48).

Further, the disclosure of *Barreras* describes the problems encountered in prior art devices and in particular describes deficiencies such as relatively broad and unfocussed electric field (sometimes resulting in undesirable motor responses), spinal chord movement with body position changes affecting the distance between the stimulating electrodes and the spinal chord and movement of the electrodes from the optimal position presenting a major problem when a patient becomes active. *Barreras* describes further deficiencies of prior art devices, namely, the inability to compensate for changes in electrode impedance due to growth of connective tissue around the electrodes, histological changes and changes in lead position which alters the distance between the electrodes and the Dura (refer column 2, lines 6 to 11).

Barreras continues to describe the problems associated with prior art devices and refers to the requirement for "a precise rate of ion flow...for pain relief." (refer column 2, lines 13 to 14).

Of course, all of these teachings of *Barreras* teach directly away from the solution claimed in the instant application.

As the claims of the instant application are clearly directed to repeatedly varying the formation of probes as active probes or return probes thus causing the establishment of repeatedly varying electrical currents passing through different paths through a subject, the claims of the instant application and the description of *Barreras* are clearly disparate and directed to solving entirely different problems.

Accordingly, the applicant respectfully submits that any one of ordinary skill in the art would not consider it obvious to modify the stimulation system as taught by *Barreras* in order to achieve the system as claimed in the instant application.

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In view of the proposed claim amendments and the response to the Office Action's observations set out above, the applicant requests favorable reconsideration of the instant application.

Conclusion

In view of the amended claims and the remarks presented above, it is respectfully submitted that all of the present claims of the application are in condition for immediate allowance. It is therefore respectfully requested that a Notice of Allowance be issued. The Examiner is encouraged to contact Applicant's undersigned attorney to resolve any remaining issues in order to expedite examination of the present application.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 13-4365.

Respectfully submitted,

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